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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,366	08/20/2001	Sandra M. Sims	3523/2/US	4928

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Pharmacia Corporation
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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	4

DATE MAILED: 03/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/933,366	SIMS, SANDRA M.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on th cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-30 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-30 are presented for prosecution on the merits.

Claim Rejections - 35 USC § 112

1. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12, lines 3-4, the phrase "e.g. methyl-beta-cyclodextrin...." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbachyn et al., 5, 688,792 and in view of Bartroli et al., 5,646,294.

Barbachyn et al. disclose antimicrobial oxazolidinone derivatives such as linezolid, wherein said compounds are formulated into compositions for treating patients suffering microbial infections. Please see col. 1, lines 5-13; col. 2, lines 21-67. The compounds may be administered orally, parenterally (by injection, intravenous injection or infusion) or topically at a dose comprising 0.1 to about 100 mg/kg of body weight. Please see col. 3, lines 1-5; col. 7, lines 33-36. The oxazolidinone compounds are combined with a solid or liquid pharmaceutically acceptable carrier and, optionally, adjuvants or excipients employing standard and conventional techniques. The compounds may be dissolved in water, water-propylene glycol and water-polyethylene glycol systems along with conventional coloring agents, flavoring agents, stabilizers and thickening agents. Please see col. 6, lines 45-65. Finally, the compositions for parenteral administration (injection) contain the oxazolidinone compounds dissolved in water and a buffer to provide a suitably buffered isotonic solution with a pH of 3.5 to 7. When the oxazolidinone derivatives are dissolved in the injectable formulations, it will be present in the range of 1 mg/ml to about 400 mg/ml of solution. Please see col. 7, lines 32-53.

Barbachyn et al. do not disclose adding a cyclodextrin compound to the composition and methods; however, the Examiner refers to Bartroli et al., which disclose orally active antifungals,

wherein said antifungals are formulated into injectable compositions containing an aqueous carrier and cyclodextrins, e.g. hydroxypropyl-beta-cyclodextrin, as solubilizing agents. Please see col. 14, lines 43-48.

It would have been obvious to one of ordinary skill in the art to modify the methods and composition of Barbachyn et al. to include the cyclodextrins taught by Bartroli et al. because Bartroli et al. disclose that the cyclodextrins enhance the solubility of the antifungal agents. Such a modification would have been motivated by the reasoned expectation of enhancing the solubility of the oxazolidinone compounds in the injectable formulations of Barbachyn et al., thereby producing a pharmaceutical composition that will be effectively delivered to the patient undergoing treatment.

Concerning the claimed concentrations of cyclodextrin, since concentration of the cyclodextrin will affect the solubility of the oxazolidinone compounds, it would have been obvious to one of ordinary skill in the art to further modify the concentration of cyclodextrins such that they are present at a concentration which is effective to optimize their solubilizing effect on the oxazolidinone compounds.

In addressing claims 9, 11 and 29, modification of the compositions and methods of the prior art to contain other know antibacterial oxazolidinone compounds would have been obvious and well within the capability of the skilled artisan. Finally, with respect to claim 15, absent evidence to the contrary, modification of the compositions and methods of the prior art to use known

cyclodextrins such as sulfobutylether-beta-cyclodextrin would have been obvious and well within the capability of the skilled artisan.

Conclusion

Claims 1-30 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

March 25, 2002

Cybille Delacroix-Muirheid
Patent Examiner Group 1600